Process:

1. Blend milled Stearic acid, ethocel, Hydrocodone Bitartrate, and Eudragit RSPO using a V-blender.
2. Extrude the mixture using a Powder Feeder, Melt Extruder (equipped with the 6×1 mm die head), Conveyor, Lasermike, and Pelletizer.
   Powder feed rate-4.2 kg/hr; vacuum-~980 mBar
   Conveyor-such that diameter of extrudate is 1 mm
   Pelletizer-such that pellets are cut to 1 mm in length
3. Screen pellets using #16 mesh and #20 mesh screens. Collect material that passes through the #16 mesh screen and is retained on the #20 mesh screen.
4. Fill size #2 clear gelatin capsules with the pellets. Range: NLT 114 mg and NMT 126 mg.

One or more aversive agents as described herein can be incorporated into a capsule with the hydromorphone pellets, into the hydromorphone pellets, or on the hydromorphone pellets by one skilled in the art. The one or more aversive agents may be in releasable, non-releasable, or substantially non-releasable form or a combination thereof. Preferably, when pellets comprising the aversive agent(s) arc incorporated into the capsule they are indistinguishable from the hydromorphone pellets.

Example 17-20

Examples 9-12 can be repeated utilizing a sufficient amount of capsaicin in place of, or in addition to the aversive agents disclosed therein.

While the invention has been described and illustrated with reference to certain preferred embodiments thereof, those skilled in the art will appreciate that obvious modifications can be made herein without departing from the spirit and scope of the invention. Such variations are contemplated to be within the scope of the appended claims.

What is claimed is:

1. A method of preparing an abuse deterrent controlled release oral dosage form comprising:

preparing a matrix comprising oxycodone or a pharmaceutically acceptable salt thereof and a gelling agent comprising polyethylene oxide having a weight-average molecular weight of about 50,000 to about 750,000; and

applying a coating comprising polyvinyl alcohol to the matrix,

the abuse deterrent dosage form forming a gel when subjected to tampering comprising dissolution in from about 0.5 ml to about 10 ml of an aqueous liquid;

the dosage form having a ratio of polyethylene oxide to oxycodone or pharmaceutically acceptable salt thereof from about 1:1 to about 30:1; and

the dosage form providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient; and

wherein the oxycodone or pharmaceutically acceptable salt thereof is the sole active agent in the dosage form.

2. The method of claim **1**, wherein the gelling agent is in an effective amount to impart a viscosity of about 10 cP or more to the gel.

3. The method of claim **1**, wherein the gelling agent is in an effective amount to impart a viscosity of about 60 cP or more to the gel.

4. The method of claim **1**, wherein the gelling agent is in an effective amount to impart a viscosity of about 120 cP or more to the gel.

5. The method of claim **1**, wherein the gelling agent is in an effective amount to impart a viscosity of about 2,000 cP or more to the gel.

6. The method of claim **1**, wherein the mixture comprises from about 2.5 mg to about 320 mg oxycodone hydrochloride.

7. The method of claim **1**, wherein the dosage form subjected to tampering is unsuitable for injection with an insulin syringe.

8. The method of claim **1**, wherein the dosage form subjected to tampering is difficult to pull into an insulin syringe.

9. The method of claim **1**, wherein the dosage form subjected to tampering cannot be filled into an insulin syringe without picking up pockets of air.

10. The method of claim **1**, wherein the dosage form subjected to tampering has a milk-like color.

11. The method of claim **1**, wherein the aqueous liquid is water.

12. The method of claim **1**, wherein the viscosity is imparted when the dosage form is subjected to tampering by dissolution in about 1 ml to about 3 ml of aqueous liquid.

13. The method of claim **2**, wherein the viscosity is imparted when the dosage form is subjected to tampering comprising crushing and dissolution in the aqueous liquid.

14. The method of claim **2**, wherein the viscosity is imparted when the dosage form is subjected to tampering comprising dissolution in the aqueous liquid at ambient temperature.

15. The method of claim **2**, wherein the viscosity is imparted when the dosage form is subjected to tampering comprising dissolution in the aqueous liquid with heating greater than 45° C.

16. The method of claim **6**, wherein the gelling agent is in an effective amount to impart a viscosity of about 10 cP or more to the gel.

17. The method of claim **6**, wherein the gelling agent is in an effective amount to impart a viscosity of about 60 cP or more to the gel.

18. The method of claim **6**, wherein the gelling agent is in an effective amount to impart a viscosity of about 120 cP or more to the gel.

19. The method of claim **6**, wherein the gelling agent is in an effective amount to impart a viscosity from about 120 cP to about 5,000 cP to the gel.

20. A method of preparing an abuse deterrent controlled release oral dosage form comprising:

preparing a matrix comprising from about 2.5 mg to about 320 mg oxycodone hydrochloride and a gelling agent comprising polyethylene oxide having a weight-average molecular weight of 50,000 to 750,000; and

applying a coating comprising polyvinyl alcohol to the matrix;

the abuse deterrent dosage form forming a gel having a viscosity of at least 10 cP when the dosage form is subjected to tampering by dissolution in from about 0.5 ml to about 10 ml of an aqueous liquid;

the dosage form having a ratio of gelling agent to oxycodone or pharmaceutically acceptable salt thereof from about 1:1 to about 30:1;

the dosage form providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient; and

wherein the oxycodone or pharmaceutically acceptable salt thereof is the sole active agent in the dosage form.

21. The method of claim **1**, wherein the gelling agent comprises a poloxamer.

22. The method of claim **20**, wherein the gelling agent comprises a poloxamer.

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